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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/008,385	11/12/2001	Carol W. Readhead	18810-81607	3519

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SIDLEY AUSTIN BROWN & WOOD  
555 West Fifth Street  
Los Angeles, CA 90013-1010

EXAMINER

PARAS JR, PETER

ART UNIT	PAPER NUMBER
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1632

DATE MAILED: 10/06/2003

5

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/008,385

Applicant(s)

READHEAD ET AL.

Examiner

Peter Paras, Jr.

Art Unit

1632

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 135-155 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 135-155 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

Art Unit: 1632

Applicant's preliminary amendment filed on 11/12/01 has been entered. Claims 1-134 have been cancelled. New claims 135-155 have been added. Claims 135-155 are pending and are under current consideration.

***Priority***

Applicant's priority statement as submitted in the preliminary amendment received on 11/12/01 contains references to related applications but does not provide the serial numbers of the related applications. Applicants should amend the priority statement to include the serial numbers of all the recited related applications.

***Specification***

The disclosure is objected to because of the following informalities: page 28 is blank.

Appropriate correction is required.

***Claim Rejections - 35 USC § 112, 1<sup>st</sup> paragraph***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 140-141 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to

one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

This rejection is directed to the recitation "operative fragment of" with respect to the recited viral vectors in claim 140.

The specification on pages 10-11 has described various viruses, which may be used to facilitate the delivery of genetic material into male germ cells. However, the specification has failed to describe the operative fragments of viruses (viral vectors), which may be used to facilitate the delivery of genetic material into male germ cells. Based upon the prior art there is expected to be structural variation among the species of viruses embraced by the claims. There is no evidence on the record of a relationship between the structure of any viral vector and the claimed "operative fragment of" that would provide any reliable information about the structure of viruses within the genus. There is no evidence on the record that the "operative fragment of" had a known structural relationship to any virus; the specification discloses various viruses on pages 10-11; the art indicated that there is structural variation between viruses. There is no evidence of record that would indicate that any of the claimed "operative fragments of" even have the capability to facilitate the delivery of genetic material into male germ cells. In view of the above considerations one of skill in the art would not recognize that applicant was in possession of the necessary common features or attributes possessed by member of the genus, because an operative fragment of a virus is not representative of the claimed genus. Consequently, since Applicant was in possession of only the disclosed viruses and since the art recognized structural variation among the species of

viruses, the operative fragment of a virus embraced by the claims was not representative of the claimed genus. Therefore, Applicant was not in possession of the genus of operative fragments of viruses encompassed by the claims. University of California v. Eli Lilly and Co., 43 USPQ2d 1398, 1404, 1405 held that to fulfill the written description requirement, a patent specification must describe an invention and do so in sufficient detail that one skilled in the art can clearly conclude that "the inventor invented the claimed invention."

***Claim Rejections - 35 USC § 112, 2<sup>nd</sup> paragraph***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 139-141, and 146 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 139 is indefinite as written. The claim recites the limitation "other uptake enhancing DNA segments", however the specification has failed to provide a definition of "other uptake enhancing DNA segments". As no definition of "other uptake enhancing DNA segments" has been provided the metes and bounds of such cannot be determined rendering the claim indefinite. Appropriate correction is required. Claims 140-141 depend from claim 139.

Claim 146 is indefinite as written. The claim as written requires spermatogonia-specific promoters but appears to embrace promoters that are not spermatogonia-specific. Appropriate correction is required.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claims 135, 136, 138, 139, 144, 147, and 150 are rejected under 35 U.S.C. 102(b) as being anticipated by Bachiller et al (Mol. Reprod. Dev., 1991, 30: 194-200).

The claims are directed to *in vitro* methods of incorporating at least one polynucleotide encoding a desired trait into a male germ cell comprising obtaining a male germ cell from a non-human vertebrate, transfecting the germ cell *in vitro* with at least one polynucleotide encoding a gene product and allowing the polynucleotide to be taken up and released into the germ cell.

Bachiller et al teach *in vitro* transfection of plasmid DNA via liposomes into mouse spermatozoa, wherein the transfection occurs at 37°C. See the abstract, Materials and Methods, and throughout the document.

Thus, the teachings of Bachiller et al anticipate all of the instant claim limitations.

Claims 135, 136, 138, 139, 144, 145, 147, 150, 151, 152 are rejected under 35 U.S.C. 102(a) as being anticipated by Kim et al (Mol. Reprod. Dev, 1997, 46: 515-526).

The claims are directed to *in vitro* methods of incorporating at least one polynucleotide encoding a desired trait into a male germ cell comprising obtaining a male germ cell from a non-human vertebrate, transfecting the germ cell *in vitro* with at least one polynucleotide encoding a gene product and allowing the polynucleotide to be taken up and released into the germ cell.

Kim et al teach *in vitro* transfection of DNA (encoding human erythropoietin and neomycin resistance) via liposomes into mouse spermatozoa, wherein the transfection occurs at 37°C. See pages 516-517, in the Materials and Methods section entitled Transfection of Spermatozoa.

Thus, the teachings of Kim et al anticipate all of the instant claim limitations.

Claims 135-145 and 147-155 are rejected under 35 U.S.C. 102(e) as being anticipated by Brinster et al (US 5,858,354).

The claims are directed to *in vitro* methods of incorporating at least one polynucleotide encoding a desired trait into a male germ cell comprising obtaining a male germ cell from a non-human vertebrate, transfecting the germ cell *in vitro* with at least one polynucleotide encoding a gene product and allowing the polynucleotide to be taken up and released into the germ cell.

Brinster et al teach a method of *in vitro* transfection primitive cells, such as spermatogonial stem cells (columns 5-7) with a heterologous DNA sequence encoding a gene of interest (column 8). Brinster et al teach that the heterologous DNA sequence can be transferred into the primitive cells by a viral vector, such as a retroviral vector or an adenoviral vector, or by liposomes. Brinster et al further teach that the DNA sequence may be obtained from a source of the same species as the primitive cells (column 8), wherein the heterologous DNA sequences are operatively linked to promoters or enhancers. Brinster et al further teach that such methods may be applicable to any species of animals including human, in which the male has testes. See column 10. Brinster et al further teach that a promoter from a gene (Zfy-1) active in developing sperm cells may be used in accordance with the described methods. See column 12.

Thus, the teachings of Brinster et al anticipate all of the instant claim limitations.



***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 135-137, 147, and 150 are rejected under 35 U.S.C. 103(a) as being unpatentable over Brinster et al (PNAS, 1994, 91: 11298-11302).

The claims are directed to *in vitro* methods of incorporating at least one polynucleotide encoding a desired trait into a male germ cell comprising obtaining a male germ cell from a non-human vertebrate, transfecting the germ cell *in vitro* with at least one polynucleotide encoding a gene product and allowing the polynucleotide to be taken up and released into the germ cell, wherein the germ cell is a spermatogonial cell or other undifferentiated male germ cell.

Brinster et al teach isolation of stem cell spermatogonia from mice.

Brinster et al differs from the claimed methods by not transfecting the isolated mouse stem cell spermatogonia.

However, at the time the claimed invention was made methods of genetically modifying mouse embryonic stem (ES) cells were well routine in the art. In fact modification of ES cells was routine as such that Brinster et al suggested that if spermatogonia could be cultured and manipulated as ES cells, then such could be used

Art Unit: 1632

in a manner similar to ES cells for creating mice with germline modifications. See page 11301, in column 2.

Accordingly, in view of the routine state of the art, as represented by Brinster et al, it would have been obvious to genetically modify the isolated mouse spermatogonia of Brinster et al by with a reasonable expectation of success. One of ordinary skill in the art would have been sufficiently motivated to make such a modification as it was an art-recognized goal to create mice with germline modifications as discussed by Brinster et al.

Thus, the claimed invention, as whole, was clearly prima facie obvious in the absence of evidence to the contrary.

### **Conclusion**

**No claim is allowed.**

Art Unit: 1632

Any inquiry concerning this communication or earlier communications from the examiner(s) should be directed to Peter Paras, Jr., whose telephone number is 703-308-8340. The examiner can normally be reached Monday-Friday from 8:30 to 4:30 (Eastern time).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Deborah Reynolds, can be reached at 703-305-4051. Papers related to this application may be submitted by facsimile transmission. Papers should be faxed via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Official Fax Center number is (703) 872-9306.

Inquiries of a general nature or relating to the status of the application should be directed to Dianiece Jacobs whose telephone number is (703) 305-3388.

Peter Paras, Jr.

Art Unit 1632

**PETER PARAS  
PATENT EXAMINER**

A handwritten signature in cursive script that reads "Pete Paras".